IN THE

Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-666

USV PHARMACEUTICAL CORPORATION, PETITIONER

v.

ELLIOTT L. RICHARDSON, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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REPLY MEMORANDUM FOR PETITIONER

Because the government has agreed that the petition for certiorari should be granted (Resp. Mem., p. 6) we need not now consider the arguments pressed in defense of the judgment below. The timetable suggested by the government in the event certiorari is granted in this and the related cases, however, requires comment.

USV concurs in the desirability of "grouping", in some logical fashion, the issues presented by these cases. But we fear that the grouping proposed by the government would result in a disorganized and unstructured over-all presentation, if adopted for oral argument.

Contrary to the government's suggestion (Resp. Mem., p. 13), the issues of statutory construction relating to the grandfather clause in the 1962 Drug Amendments (the questions presented in this case and Question 4 in the *Hynson* cross-petition [1]) are entirely distinct from *Hynson's* Question 2. That question relates to whether an evidentiary hearing would be required in administrative proceedings to decide if a product is a "new drug", assuming that the agency rather than the court is the proper forum. *Hynson's* Question 2 should appropriately, therefore, be grouped with the government's petition in *Hynson*,[2] which puts in issue the circumstances in which an evidentiary hearing is required in administrative proceedings to decide the actual safety and effectiveness of drugs. Consolidated oral argument on *Hynson's* issue of proper adjudicatory procedure and on the questions presented in *USV* as to the substantive criteria for grandfather protection would confuse, rather than clarify, this complex and important litigation.

There is also need to modify the government's further proposal to curtail oral argument on the substantive questions of interpreting the grandfather clause. In total, at least three separate such issues are

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[1] *Hynson, Westcott & Dunning, Inc.* v. *Richardson*, No. 72-414, *petition for certiorari filed*, Sept. 11, 1972.

[2] *Richardson* v. *Hynson, Westcott & Dunning, Inc.*, No. 72-394, *petition for certiorari filed*, Sept. 7, 1972.

tendered by the two petitions in this group (the present case and the *Hynson* cross-petition, No. 72-414). Only one of these issues is even partly common to both petitions (Question 1 in *USV* and Question 4 in the *Hynson* cross-petition), and even with respect to that common element the rationales of the respective petitioners are different.[3]

We suggest, therefore, that oral argument would be most helpful to the Court if the usual one hour were allowed in the present case. The effect would merely be to increase the total time allowed for oral argument in these cases from the three and one-half hours proposed by the government to four hours.

Finally, we suggest that, if the petitions for certiorari are granted, the "jurisdictional" issues presented by *Bentex* (No. 72-555) and *Ciba* (No. 72-528), relating to the respective roles of court and agency, should be argued first. We propose that the "jurisdictional" argument be followed immediately by oral argument on the issues of statutory construction arising under the grandfather clause presented here and in *Hynson* (No. 72-414), leaving for last the issues of hearing procedure presented by the two petitions in *Hynson*.

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[3] Hynson appears to argue that when a drug became no longer "new" prior to 1962 it was *ipso facto* no longer "covered by an effective [new drug] application", while our approach concedes arguendo that "there must be some further action which removes the product from new-drug regulation, before it can be found the product is no longer 'covered' by an effective NDA" (Pet., p. 18). Moreover, only the *USV* petition (Question 2) presents the issue of the status of up to 13,000 "me-too" products. Conversely, we do not raise *Hynson's* Question 3 as to the authority of FDA to conduct proceedings to withdraw approval of pre-1962 NDA's for products protected by the grandfather clause.

This sequence of argument, because it tracks logical sequence of issues as they normally would reached in a given case, would promote clarity in p sentation and assist the Court in examining the en regulatory framework in which these related c arise.

Counsel for Bentex Pharmaceuticals, Inc. *et al.* (spondents in No. 72-555) and for Ciba Corp. (p tioner in No. 72-528) have authorized us to state t they join in the foregoing suggestion for the sequen of oral argument in these cases if the petitions f certiorari are granted.

Respectfully submitted,

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January 3, 1973

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CITATIONS

In the Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-394

CASPAR W. WEINBERGER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS, PETITIONERS

v.

HYNSON, WESTCOTT AND DUNNING, INCORPORATED

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (J.A. 173-180)[1] is reported at 461 F. 2d 215. The order of the Commissioner of Food and Drugs was published in the Federal Register on June 18, 1971 (J.A. 72-78; 36 Fed. Reg. 11763).

[1] "J.A." refers to the Joint Appendix filed by the parties in this case and in Nos. 72-414, 72-528, 72-555, and 72-666, with which this case has been consolidated.

JURISDICTION

The judgment of the court of appeals (J.A. 181) was entered on May 24, 1972. The petition for a writ of certiorari was filed, pursuant to an extension of time granted by Mr. Justice Rehnquist, on September 7, 1972. On January 8, 1973, this Court granted the petition and consolidated the case with four other cases in which it also granted writs of certiorari.[2] The jurisdiction of this Court rests on 28 U.S.C. 1254(1) and 21 U.S.C. 355(h).

QUESTION PRESENTED

Whether the Commissioner of Food and Drugs may, in implementing the drug effectiveness requirements of the 1962 amendments to the Food, Drug, and Cosmetic Act of 1938, withdraw approval for the marketing of a drug for lack of proof of effectiveness, without a hearing, if the manufacturer has failed to comply with the Commissioner's regulations requiring that a request for hearing must be supported by a showing that it is prepared to produce the kind of "substantial evidence" of effectiveness required by the statute.

STATUTORY PROVISIONS AND REGULATIONS INVOLVED

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) (J.A. 479) provides in pertinent part:

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[2] The other cases are *Hynson, Westcott and Dunning, Incorporated* v. *Caspar W. Weinberger, et al.*, No. 72-414; *CIBA Corporation* v. *Caspar W. Weinberger, et al.*, No. 72-528; *Caspar W. Weinberger, et al.* v. *Bentex Pharmaceuticals, Inc., et al.*, No. 72-555; and *USV Pharmaceutical Corporation* v. *Caspar W. Weinberger, et al.*, No. 72-666.

> The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds * * * (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect its purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling thereof * * *.

Section 505(d) (21 U.S.C. 355(d)) (J.A. 478) provides in pertinent part:

> * * * As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

Pertinent provisions of the regulations of the Commissioner of Food and Drugs, 21 C.F.R. 130.12(a)(5) and 130.14, as amended, 35 Fed. Reg. 7251, 7252, are set forth at J.A. 487–491.